

IN THE
UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

ASSOCIATION FOR ACCESSIBLE MEDICINES,

Plaintiff-Appellee,

vs.

KEITH ELLISON, in his official capacity as
Attorney General of the State of Minnesota,

Defendant-Appellant.

**ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA**

APPELLANT'S REPLY BRIEF

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ARGUMENT

The question before this Court, that AAM never answers, is whether the dormant Commerce Clause severs state police powers whenever a manufacturer prefers to send its products into a state through third-party wholesalers, rather than directly?

Ignoring the question and the context required to answer it, AAM repeats *ad nauseum* its claim that the Act is *per se* unconstitutional because it ‘directly regulates wholly out-of-state commerce.’ Response Br. *passim*. To enable this conclusion, AAM misconstrues the Act as regulating transactions between an out-of-state seller and an out-of-state distributor for drugs that are not bound for, and never reach, Minnesota’s marketplace. Freed from the complexities of the actual Minnesota market and comprehensive regulatory regimes that govern it, AAM conjured this hypothetical and tailored its injunction to look like decades old cases striking down overbroad or discriminatory milk, beer, and corporate takeover laws.

The Act, however, does not fit neatly into their dream scenario. It sits atop Minnesota’s pharmaceutical regulatory regime that, for decades, has governed the conduct of every in- and out-of-state actor in the drug supply chain that wishes to access Minnesota’s marketplace. AAM does not dispute this. To be sure, the prescription drug market relies on numerous in- and out-of-state actors that play a role in the production, distribution, dispensing, prescription, and sales of drugs to

consumers. To access and participate in Minnesota’s prescription drug market, however, each and every actor in this supply chain must hold a license from its Board of Pharmacy. And despite AAM’s attempted distortions, the Act only applies when every actor in the supply chain has chosen to play by the rules of Minnesota’s prescription drug regulatory scheme, *and* only as to those drugs that actually enter and are sold, delivered, or dispensed to a consumer in Minnesota.

Adopting AAM’s hypothetical, the district court enjoined the Act’s application to transactions between (Minnesota-licensed) out-of-state manufacturers and (Minnesota-licensed) out-of-state distributors for drugs bound for Minnesota’s marketplace—relying on the same precedent that AAM raises here. The injunction relies on a misreading of the dormant Commerce Clause and opens the door for any out-of-state actor to avoid any state’s regulation simply by placing another out-of-state intermediary between themselves and the regulating state. But Minnesota’s police powers are not so easily cast aside. Indeed, the district court’s reliance on extraterritoriality-doctrine case law was mistaken because the legal landscape has changed significantly.

AAM does not contend the Act is discriminatory, and AAM’s *Pike*-balancing claim remains in the district court. Accordingly, neither of the dormant Commerce Clause’s limitations on state police power are implicated by this appeal. *Mallory v. Norfolk S. Ry. Co.*, 600 U.S. 122, 160 (2023) (Alito, J., concurring in part and

concurring in the judgment) (citation omitted) (“Under our modern framework, a state law may offend the Commerce Clause’s negative restrictions in two circumstances: when the law discriminates against interstate commerce or when it imposes ‘undue burdens’ on interstate commerce.”). Therefore, AAM’s claim before this Court requires examining whether the Act violates what shreds remain, if any, of the dormant Commerce Clause’s extraterritoriality doctrine following the Supreme Court’s decisions in *National Pork Producers Council v. Ross*, 598 U.S. 356 (2023), and *Mallory*.

As the Supreme Court’s *Ross* decision explains, the dormant Commerce Clause no longer provides authority for standalone extraterritoriality challenges to nondiscriminatory state laws, a fact confirmed by *Mallory*. The Act before this Court should therefore be upheld as constitutional. AAM’s arguments fail for several reasons:

I. The trio of cases that once formed the backbone of the dormant Commerce Clause’s ban on nondiscriminatory laws that directly regulate out-of-state commerce – *Baldwin v. G.A.F. Seelig, Inc.*,¹ *Brown-Forman Distillers Corp. v. New York State Liquor Auth.*,² and *Healy v. Beer Institute, Inc.*³ – have been recast; the Supreme Court directs that these cases more narrowly exemplify the dormant

¹ *Baldwin*, 294 U.S. 511 (1935).

² *Brown-Forman*, 476 U.S. 573 (1986).

³ *Healy*, 491 U.S. 324 (1989).

Commerce Clause’s traditional ban on laws that *discriminate* against out-of-state commerce, and thus, do not apply to the Act.

II. This refined doctrinal landscape requires reassessing this Court’s decision in *Styczinski v. Arnold*,⁴ the Supreme Court’s *Edgar v. MITE Corp.*⁵ decision, and Fourth Circuit’s take on a similar law in *Association for Accessible Medicines v. Frosh*.⁶ Because each rely on the *Baldwin*, *Brown-Forman*, and *Healy* trio, they do not dictate the Act’s constitutionality.

III. Even before *Ross*, federal courts permitted states to directly regulate out-of-state transactions when they impacted consumers within the regulating state. Like these regulations, the Act only regulates voluntary and licensed participants in the in-state market, and only when their drugs are delivered, dispensed, or sold in Minnesota.

IV. AAM advances numerous irrelevant arguments that do not alter the answer to the narrow question before this Court. At most, such arguments are only relevant to AAM’s *Pike* balancing and Due Process claims, which are not before this Court.

⁴ *Styczinski*, 46 F.4th 907 (8th Cir. 2022).

⁵ *Edgar*, 457 U.S. 624, (1982).

⁶ *Frosh*, 887 F.3d 664 (4th Cir. 2018).

The Act is an expression of Minnesota’s sovereign police powers, exercised to protect the health of Minnesotans by ensuring generic drugs are not priced out of reach for consumers in Minnesota. The Act’s scope and breadth align with a half-century of state regulation of pharmaceutical manufacturers. AAM’s effort to constitutionalize its business decision to use out-of-state distributors to avoid in-state regulations threatens to undermine state police powers to protect public health and welfare by imposing conditions on goods entering their jurisdictions.

Because the Act only regulates transactions between actors that chose to establish substantial in-state connections with Minnesota, it does not violate whatever is left of the dormant Commerce Clause’s extraterritoriality doctrine. This Court should reverse the decision of the district court, vacate the preliminary injunction, and remand for further proceedings.

I. *BALDWIN, BROWN-FORMAN, HEALY*, AND THEIR PROGENY DO NOT APPLY.

In *Ross*, the U.S. Supreme Court corrected lower courts’ broad overreading of its holdings in *Baldwin*, *Brown-Forman*, and *Healy*. These cases, a unanimous Court said, do not stand for the proposition that any state law regulating out-of-state prices were forbidden by an ‘almost *per se*’ rule under the dormant Commerce Clause. *Ross*, 598 U.S. at 376. Rather, each law’s cardinal sin was “a *specific* impermissible ‘extraterritorial effect’—they deliberately ‘prevented out-of-state firms from undertaking competitive pricing’ or ‘deprived businesses and consumers in other

states of ‘whatever competitive advantages they may possess.’ *Id.* at 374 (cleaned up) (emphasis in original). Accordingly, these laws violated the dormant Commerce Clause because each “typifies the familiar concern with preventing purposeful discrimination against out-of-state economic interests.” *Id.* at 371. But, the Court cautioned, the dormant Commerce Clause is not an all-purpose tool to address *any* (i.e., non-discriminatory) law simply because it regulates beyond state boundaries. *Id.* at 376. Therefore, *Baldwin*, *Brown-Forman*, and *Healy* do not “cast a shadow” over the “immense mass of inspection laws, quarantine laws, and health laws of every description that have a considerable influence on commerce outside their borders.” *Id.* at 375.

AAM does not allege that Minnesota’s Act is discriminatory.⁷ They only allege the Act directly regulates out-of-state transactions that, under pre-*Ross* precedent, is *per se* unconstitutional. Resp. Br. 22. Neither *Baldwin*, *Brown-Forman*, *Healy*, nor *Ross* support AAM’s contention.

⁷ 1-App.-3-33; (R.Doc. 1, at 1-31). 3-App.-603-05; (R.Doc. 39, at 55-6).

II. *STYCZYNSKI*, *FROSH*, AND THE *EDGAR* PLURALITY DO NOT DICTATE THE OUTCOME OF THIS APPEAL.

Ross’s recharacterization of the *Baldwin*, *Brown-Forman*, and *Healy* trio requires a reassessment of *Styczynski*, the *Edgar* plurality, and *Frosh*.⁸ Each relied on *Baldwin*, *Brown-Forman*, and/or *Healy* to strike down nondiscriminatory laws without engaging in *Pike* balancing. But just as Ross has clarified and narrowed the application of those underlying cases, so, too, must this Court analyze the Act through a modern dormant Commerce Clause lens that has all-but-eliminated the extraterritoriality doctrine.⁹

A. AAM’s Mistaken Reliance on *Styczynski*.

AAM’s principle defense of the district court’s injunction rests heavily on a misreading of *Styczynski*, this Court’s pre-Ross decision striking down parts of

⁸ *Edgar v. MITE Corp.*, 457 U.S. 624, 641-43 (1982) (“*Edgar* plurality”). The *Edgar* plurality must be distinguished from *Edgar*’s majority decision, where the Supreme Court struck down the Illinois law under *Pike* balancing. *Id.* at 643-46.

⁹ AAM claims a majority of the Ross court found that “plaintiffs *had* adequately alleged that the California law imposed a substantial burden on interstate commerce, even though the plaintiffs expressly disclaimed any theory of discrimination.” Resp. 33 n.21. This is simply incorrect. *See Ross*, 598 U.S. 356, 403 (Kavanaugh, J., concurring in part and dissenting in part) (“Part IV–C of Justice GORSUCH’s opinion is controlling precedent for purposes of the Court’s judgment as to the plaintiffs’ *Pike* claim. ... The plurality reasons that the plaintiffs’ complaint did not sufficiently allege that the California law at issue here imposed a substantial burden on interstate commerce under *Pike*.”) The district court echoed AAM’s mistaken reading at oral argument, 3-App.-585 (R.Doc. 39 at 37), but reached the correct conclusion in its decision. *See Add.* 23 (R.Doc. 42 at 23).

Minnesota’s bullion registration law that are distinguishable from the Act. Moreover, because *Styczynski* relied principally on *Healy*, its authoritative value must be reassessed post-*Ross*.

i. The *Styczynski* Bullion Law Was Plainly Overbroad.

Styczynski is one of the last pre-*Ross* appellate cases striking down a nondiscriminatory state law under the dormant Commerce Clause. Whether *Styczynski* remains good law – as even the district court in *Styczynski* questioned on remand – is an open question.

In *Styczynski*, this Court found two extraterritoriality problems in the bullion law, but neither are present in the Act. First, the bullion law cloaked Minnesota citizens with its regulatory protection even when they left Minnesota and engaged in a qualifying bullion transaction in another state. *Styczynski*, 46 F.4th at 913 (regulating any transaction “between a dealer and a consumer who lives in Minnesota.”) Second, the bullion law required coin dealers, wherever located, to register with the state and post a surety bond if they ever sold \$25,000 in coins to a Minnesota citizen anywhere in the world. *Id.* For previously unlicensed dealers, Minnesota’s registration requirement was imposed after-the-fact under threat of criminal charges. *Id.* The commonality between these two concerns is that out-of-state traders were ensnared in Minnesota’s regulatory scheme, and faced liability, without ever “set[ting] foot” in Minnesota. Resp. Br. 26.

But here, manufacturers *have* affirmatively chosen to set foot in Minnesota for over 50 years in order to obtain permission to legally distribute their drugs here. *See* Minn. Stat. § 151.252, subd. 1(g) (requiring out-of-state manufacturers to obtain license for “each facility located outside of the state at which drugs that are shipped into the state are manufactured”). AAM’s members are simply not in the position of an out-of-state bullion trader that never sought to access Minnesota’s bullion market (or purposefully sought to avoid it), and did not otherwise voluntarily subject themselves to Minnesota’s bullion regulations.

The extraterritoriality problems identified in *Styczinski* were due to the bullion law’s overbroad plain language that permitted wholly out-of-state applications. Sloppy drafting was the culprit, which is evident from the district court’s treatment of the statute on remand. *See Styczinski v. Arnold*, No. 20-CV-2019 (NEB/TNL), 2024 WL 1694056, at *4 (D. Minn. Mar. 29, 2024) (severing portions of the law that with wholly extraterritorial applications but otherwise letting the law stand), *appeal docketed* No. 24-1828.

Again, neither of *Styczinski*’s extraterritoriality problems are present in the Act. The Act only applies to manufacturers that voluntarily sought out and obtained licenses from Minnesota’s Board of Pharmacy for the express purpose of making their drugs available in Minnesota. Likewise, when Minnesota-licensed

manufacturers rely on distributors to deliver their drugs into Minnesota, those entities must also hold Minnesota licenses.

Further, the Act only applies when Minnesota-licensed manufacturers impose excessive price increases on drugs bound for Minnesota’s marketplace—specifically, when those drugs are sold, distributed, or dispensed to consumers in Minnesota. Accordingly, the Act only ever regulates transactions of parties that have a substantial connection to Minnesota, and only when their products are harmful to consumers in Minnesota.

ii. *Styczinski* (Relying on *Healy*) Applied a Broad *Per Se* Extraterritoriality Rule Subsequently Rejected by *Ross*.

Ross’s refinement of the dormant Commerce Clause landscape has been widely noted. Decided after this Court remanded *Styczinski*, *Ross* prompted the district court to question whether *Styczinski* was still authoritative:

“There is a good argument that the entire statute is constitutional under the dormant Commerce Clause following [*Ross*], given the Court’s characterization of the dormant Commerce Clause jurisprudence and recharacterization of *Healy*, especially because *Healy* laid the foundation of the Eighth Circuit’s extraterritoriality jurisprudence and the Eighth Circuit’s decision here.”

Styczinski v. Arnold, No. 20-CV-2019 (NEB/TNL), 2024 WL 1694056, at *3 (D. Minn. Mar. 29, 2024).

In *Styczinski*, this Court relied on language from *Healy* that the Supreme Court in *Ross* warned against overreading, because it “appeared in a particular context and

did particular work.” *Ross*, 598 U.S. at 374 (rejecting petitioner’s reading of *Healy* at 491 U.S. at 336 to a nondiscriminatory state law); *cf. Styczinski* (applying reasoning from *Healy* at 491 U.S. at 336 to strike down nondiscriminatory state law). *Ross* explained that the law in *Healy* violated the dormant Commerce Clause because it was a *discriminatory* extraterritorial law that only applied to out-of-state firms. *Ross*, 598 U.S. at 373.

But simply calling a law ““direct” regulation of interstate commerce does not make it per se unlawful.” *Southern Union Co. v. Missouri Pub. Serv. Comm’n*, 289 F.3d 503, 508 (8th Cir. 2002) (upholding state law regulating out-of-state stock transactions to protect in-state consumers). The district court found, and AAM concedes, the Act at issue here is nondiscriminatory because it falls on in- and out-of-state firms alike. *See* 3-App.-603-4; (R.Doc. 39 at 55-56). Thus, to the extent *Styczinski* rests on *Healy*’s application to a nondiscriminatory extraterritorial law, neither case guides this Court’s review of the undisputedly nondiscriminatory Act.

iii. AAM Disguises Inapposite *Pike* Balancing Authority to Defend the District Court’s Injunction.

AAM claims that six justices in *Ross* held the door open for *some* dormant Commerce Clause applications to nondiscriminatory state laws. Resp. Br. 32-33. AAM neglects to mention, however, that *Ross*’s discussion related only to the continued, albeit rare, instances when the dormant Commerce Clause’s *Pike* balancing test could apply to even genuinely nondiscriminatory laws. *Ross*, 598 U.S.

at 396 (Roberts, C.J., concurring in part and dissenting in part) (citations omitted) (“we generally leave the courtroom door open to plaintiffs invoking the rule in *Pike*, that even nondiscriminatory burdens on commerce may be struck down on a showing that those burdens clearly outweigh the benefits of a state or local practice.”). The district court said the same. *See* Add. 22 (R.Doc. 42 at 22).

Further, the Attorney General never conceded that the dormant Commerce Clause applies to nondiscriminatory extraterritorial state laws absent *Pike* balancing.¹⁰ The Attorney General simply noted *Ross*’s effort to distance the *Edgar* plurality from more established dormant Commerce Clause principles because, despite the plurality’s use of dormant Commerce Clause nomenclature, it did not seek to combat discriminatory protectionism or burdensome extraterritorial regulations, like every other dormant Commerce Clause case the Court has ever decided. *Ross*, 598 U.S. at 376, n.1.

AAM’s *Pike* balancing claim is not before this Court on appeal, and *Ross* does not support their claim that the dormant Commerce Clause will strike down nondiscriminatory state laws *without* “a showing that those burdens [on commerce] clearly outweigh the benefits of a state or local practice” under the *Pike* balancing framework. *Id.*

¹⁰ *See* Opening Br. 21 & n.75. *Contra* Resp. Br. 32.

B. The Supreme Court Categorizes *Edgar* as a *Pike* Balancing Case, Doubting The *Edgar* Plurality’s Continued Applicability To Dormant Commerce Clause Claims.

Without the *Baldwin*, *Brown-Forman*, *Healy* trio, AAM’s argument relies entirely on the *Edgar* plurality, which has also been reframed by the Supreme Court. In two decisions just last year, the U.S. Supreme Court distanced the *Edgar* plurality’s extraterritoriality rationale from the Court’s current dormant Commerce Clause jurisprudence.

First in *Ross*, the Court briefly described the law at issue in *Edgar* as one that “*directly* regulated out-of-state transactions by those with *no* connection to the State,” and questioned whether such a law even implicates the dormant Commerce Clause. *Ross*, 598 U.S. at 376 n. 1 (emphasis in original). The *Edgar* majority, however, was cited by at least six justices to support *Ross*’s holding that even nondiscriminatory state laws can, in rare cases, be subject to *Pike* balancing. *Id.* at 392, 396.

The second time, in *Mallory*, Justice Alito described *Edgar* as a case involving a state law that merely failed to satisfy the *Pike* balancing standard.¹¹ As Justice Alito explained, the law failed *Pike*-balancing because a “State generally does not have a legitimate local interest in vindicating the rights of non-residents harmed by

¹¹Again, AAM’s *Pike*-balancing claim is not before this Court.

out-of-state actors through conduct outside the State,” and thus, any burden the Illinois law had on purely out-of-state transactions was unconstitutional. *Mallory*, 600 U.S. at 163 (2023) (Alito, J., concurring in part and concurring in the judgment) (citing *Edgar v. MITE Corp.*, 457 U.S. 624, 644, (1982)). When there is no legitimate local interest served by regulating transactions with absolutely no connection to the state, “there is nothing to be weighed in the balance to sustain the law.” *Edgar*, 457 U.S. at 644. Despite the debate over the remaining legitimacy (if any) of the *Edgar*’s plurality’s extraterritoriality analysis, *Edgar*’s majority struck down the Illinois law with a straightforward application of *Pike* balancing; because one side of the scale was missing—the legitimate local interests—the Illinois law imposed an unconstitutional *burden* on interstate commerce.

The takeaway from the Supreme Court’s re-characterizations of *Edgar* in *Ross* and *Mallory* shows that the Constitution’s prohibition on extraterritoriality no longer resides in the dormant Commerce Clause.¹² Because the district court relied on the *Edgar* plurality’s erroneous extraterritoriality analysis under the dormant Commerce Clause, it is legally unsound. Accordingly, this Court should reverse the district

¹²See *Ross*, 598 U.S. at 376 n. 1 (distinguishing *Edgar v. MITE Corp.* from traditional dormant Commerce Clause decisions in *Baldwin*, *Brown-Forman*, and *Healy*); *Mallory*, 600 U.S. at 160 (Alito, J., concurring in part and concurring in the judgment); see also, Jack Goldsmith & Eugene Volokh, *The Relevance of Ross to Geolocation and the Dormant Commerce Clause*, 102 Tex. L. Rev. Online 30, 35 (2023) (“*Ross* announces that a standalone extraterritoriality test is not part of the [dormant Commerce Clause] analysis.”).

court's preliminary injunction, to determine whether the Act is subject to AAM's *Pike* balancing or Due Process claims.

C. The *Edgar* Plurality is Inapplicable Here.

Despite the Supreme Court's recent reframing of *Edgar*, AAM relies heavily on the *Edgar* plurality's questionable extraterritoriality analysis. AAM argues the law and regulated transactions in *Edgar* actually had substantial Illinois connections, just not "substantial enough" to save it from the axe of the dormant Commerce Clause. Resp. Br. 41-42. AAM is not wrong about the facts in *Edgar*, just the conclusions it draws from them. The Court's primary concern in *Edgar* was the breadth of the law's plain language, which permitted applications to parties and conduct with no in-state connection even though it had other lawful applications. In other words, just like the bullion law in *Styczinski*, the Illinois law was overbroad.

To be clear, the law at issue in *Edgar* is factually distinguishable from the Act. The law in *Edgar* allowed Illinois to completely block a *nationwide* sale of shares in publicly traded businesses so long as Illinois shareholders owned 10% of the equities subject to the offer *or* two of three Illinois-nexus factors were met. . *Edgar*, 457 U.S. at 627. Accordingly, a wholly out-of-state company making an offer on another wholly out-of-state company was subject to Illinois regulation if some Illinois residents had purchased stock in the company subject to the offer, even if those Illinois residents had purchased those shares physically on the floor of the New York

Stock Exchange. *Id.* Thus, *Edgar*'s plurality had an identical concern to one this Court expressed in *Styczinski*; a state law's plain language permitted applications to parties and conduct with absolutely no connection to the regulating state at all (i.e., the citizenship of a single party is not enough). Moreover, the *Edgar* court was concerned that the Illinois law purported to protect even out-of-state shareholders, *id.* at 642, something the Act does not attempt to do.

In *Edgar* and *Styczinski*, the laws overbroadly extended to protect out-of-state actors from the purportedly harmful effects of out-of-state transactions. The Act here does not suffer these overbreadth problems. It does not bar out-of-state manufacturers from imposing excessive price increases on its drugs in any other state. Here, the Act only ever regulates out-of-state transactions when those transactions harm individuals¹³ in Minnesota through the assessment of exorbitant price increases on generic prescription drugs. Moreover, the only entities held liable for these acts are manufacturers who specifically sought licenses from the State of

¹³ AAM speculates that drugs dispensed to consumers for free would still violate the Act, despite causing no harm at all. Resp. Br. 2, 20, 31. AAM's premise is false. The Act is part and parcel of a regulatory scheme protecting more than just individual end users. It protects pharmacies, hospitals, and other actors in the distribution chain in Minnesota from absorbing or passing on the costs of manufacturer price-gouging. If a Minnesota hospital dispenses overpriced drugs to patients for free, it is not harm-free; the hospital eats the costs of manufacturer price-gouging. That end-users benefit from third-party charity or benevolence does not excuse unlawful price-gouging. The harm from car theft does not disappear because victim's friends generously replace their car.

Minnesota to sell, distribute, or dispense those drugs in Minnesota, which is the very activity the Act regulates.¹⁴

Constitutionally, the Act is not an outlier. The Supreme Court found Indiana’s interest in the corporate governance of its domestic corporations sufficient to withstand a dormant Commerce Clause challenge. *CTS Corp. v. Dynamics Corp. of Am.* 481 U.S. 69, 94 (1987). This Court found “Missouri’s interest in assuring a reliable and affordable supply of natural gas for its citizens” sufficient to withstand a dormant Commerce Clause challenge to its regulation of out-of-state stock transactions at a utility’s Texas headquarters. *Southern Union Co.*, 289 F.3d at 509.

Surely, then, Minnesota’s interest in assuring consumer access to affordable generic drugs is sufficient to withstand a dormant Commerce Clause challenge to its regulation of out-of-state actors who choose to do business and direct their products into Minnesota. The lengthy history of state-level prescription drug regulation in this country establishes that Minnesota has a legitimate interest in protecting local consumers by regulating the price of drugs they need to survive.

¹⁴ AAM builds a strawman to claim that Minnesota licensure “to distribute one product in Minnesota does not give Minnesota jurisdiction over every product in the catalog.” Resp. Br. 36. The Attorney General never claimed the Act reaches every drug a licensed manufacturer produces. The Act does not do this. The Act only applies to drugs sold, distributed, or dispensed *in Minnesota*. If a manufacturer only sends one excessively priced drug to Minnesota, that is the only one of the manufacturer’s drugs the Act will regulate.

D. *Frosh* Relied on a Broad Per-Se Extraterritoriality Rule *Ross* Rejected.

The *Frosh* decision rested on the overbroad language of the law and a now-rejected theory of extraterritoriality. 887 F.3d at 671 (noting that the Maryland “Act’s plain language allows Maryland to enforce the Act against parties to a transaction that did not result in a single pill being shipped to Maryland”). *Frosh* considered a Maryland law even broader than the bullion law in *Styczinski*, which at least required the transaction to include a Minnesota resident. As the district court in this case recognized, the Maryland law in *Frosh* had a “slightly broader reach than the Act,” because it “could be triggered without an actual sale or distribution of a drug in Maryland” while, by contrast, the Act here “is not triggered until a drug is ‘sold, dispensed, or delivered any consumer’ in Minnesota.” Add. 13-14; (R.Doc. 42 at 13-14). This difference dispositively distinguishes the laws in *Frosh* and *Styczinski* from the Act here.

Moreover, *Frosh*’s dissent would have upheld Maryland’s law and presciently predicted the extraterritoriality doctrine’s downfall. 887 F.3d 665, 681 (questioning “the extraterritoriality doctrine’s continuing vitality.”) (Wynn, J., dissenting). Just five years later, *Ross* sounded the death knell of any *per se* ban on extraterritorial laws. *Ross*, 598 U.S. 356, 376. Under a historically-minded review of commerce, the *Frosh* dissent pointed out that commerce occurring within a state’s borders

naturally included upstream transactions. *Frosh*, 887 F.3d at 683 (Wynn, J., dissenting).¹⁵

Here, the Act regulates only those manufacturers that have voluntarily chosen to license themselves in Minnesota to have their drugs legally distributed here, and the Act is only triggered when such manufacturers' excessively priced drugs are sold dispensed, or delivered to an actual Minnesotan living inside Minnesota. The Act does not require manufacturers to price drugs differently for drugs bound to other states. This Court need not determine whether *Frosh* was, with the retrospective clarity of *Ross*, decided correctly to uphold the Act. The Act is distinctly different from the Maryland law and can be upheld consistent with the analysis in *Frosh*.

Stitching together obsolete analyses from *Styczynski*, the *Edgar* plurality, and *Frosh*, AAM attempts to resurrect a broad extraterritoriality doctrine under the dormant Commerce Clause providing that direct regulation out-of-state commerce is *per se* unconstitutional. The Court in *Ross* and *Mallory* did away with the *per se* rule, to which AAM clings. Modern dormant Commerce Clause jurisprudence, as

¹⁵ *Frosh*'s dissent noted the position of "then-Judge, now Justice Gorsuch" in distinguishing *Healy* and other discriminatory price-affirmation statutes from those laws, like Minnesota's Act, that do nothing to modify the prices charged to consumers in other states. *Frosh*, 887 F.3d at 686 (Wynn, J., dissenting). Of course, Justice Gorsuch went on to make very similar points in *Ross*, upholding California's law with major extraterritorial effects. *See Ross*, 598 U.S. at 372-73.

recently clarified by the Supreme Court, requires reversal of the preliminary injunction and remand.

III. FEDERAL COURTS DO NOT UNIFORMLY REJECT STATE EFFORTS TO REGULATE PRESCRIPTION DRUG PRICES.

AAM's contention that federal courts unanimously reject states' efforts to regulate prescription drug prices is no longer true (if it ever was). Resp. Br. 26-28 n.18. The Supreme Court rejected an identical argument to a similar state law mandating payments from drug manufacturers to offset the retail price paid by residents inside Maine. *Pharm. Rsch. & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 670 (2003).

In *Walsh*, like AAM here, PhRMA claimed the dormant Commerce Clause's purported *per se* extraterritoriality rule from *Baldwin* and *Healy* prohibited Maine's law because it regulated the "terms of transactions that occur" between out-of-state manufacturers and out-of-state wholesalers. *Id.* at 669-70. PhRMA's argument in *Walsh* is functionally identical to AAM's:

Maine mandates payments from manufacturers whose only transactions leading to the pharmacy counter are with wholesalers. To the extent that those sales occur outside Maine-and virtually all manufacturers' sales do-Maine cannot mandate the Maine Rx payments consistent with the Commerce Clause. The only link to the state is that the goods flow through a stream of interstate commerce that the manufacturers do not control and ultimately come to rest on a pharmacy counter in Maine.

See Brief for Petitioners at 28, *Pharm. Research & Mfrs. of Am. v. Concannon*, 538 U.S. 644 (2003) (No. 01-188), 2002 WL 31120844 (emphasis added).

The Court rejected PhRMA’s extraterritoriality argument directly, simply saying that “[t]he rule that was applied in *Baldwin* and *Healy* ... is not applicable to this case.” *Walsh*, 538 U.S. at 669. And, to the extent *Walsh* left open the possibility of a freestanding dormant Commerce Clause ban on nondiscriminatory extraterritorial laws, *Ross* knocked it down.

Further, nondiscriminatory state laws regulating out-of-state drug manufacturers have survived dormant Commerce Clause challenges. *See, e.g., In re Brand Name Prescription Drugs Antitrust Litig.*, 123 F.3d 599, 613 (7th Cir. 1997); *K-S Pharms., Inc. v. Am. Home Prods. Corp.*, 962 F.2d 728, 731 (7th Cir. 1992). As Judge Easterbrook noted in *K-S Pharmacies*, a pricing law is unconstitutional when it limits prices charged to consumers in other states, but not when the company remains free to price as it pleases elsewhere. 962 F.2d at 730.

With *Ross*’s re-characterization of *Healy*, no daylight exists between the *Walsh* Court’s approval of Maine regulating transactions between out-of-state drug manufacturers and out-of-state wholesale distributors to ensure affordable drugs for in-state consumers, and Minnesota’s regulation of transactions between out-of-state drug manufacturers and out-of-state wholesale distributors to protect consumers in Minnesota from price gouging. The former was upheld by the Supreme Court, and the latter should be revived by this Court.

IV. AAM’S NUMEROUS ARGUMENTS ARE IRRELEVANT TO THE NARROW EXTRATERRITORIALITY ISSUE BEFORE THIS COURT.

AAM weaves a number of arguments into its Response irrelevant to the narrow question before the Court.

A AAMs Members and Distributors Have Substantial Minnesota Connections.

AAM blurs the record to suggest its members sell to wholesale distributors with no presence in Minnesota. Resp. Br. 30-31. To be sure, “none of the three largest wholesale distributors who control over 90% of the market—AmerisourceBergen,¹⁶ Cardinal Health, and McKesson—is incorporated or headquartered in Minnesota,” but each hold wholesale distributor licenses from Minnesota’s Board of Pharmacy and have brick and mortar locations in Minnesota. *See* 1-App.-14 (R.Doc. 1 at 12 ¶26); AmerisourceBergen 3-App-526 (R.Doc. 27-3 at 8); Cardinal Health 3-App.-521-522, 528 (R.Doc. 27-3 at 3-4, 10); McKesson 3-App.-520 (R.Doc. 27-3 at 2). This is precisely how many of AAM’s members make their drugs available in Minnesota.

AAM misleadingly asserts that “none of its regular members is based in Minnesota” even though each hold licenses they sought from Minnesota’s Board of Pharmacy to have their drugs sold in Minnesota, or to engage in the distribution of other drugs in the state.

¹⁶ “Cencora” is AmerisourceBergen’s new name. Resp. Br. 9-10 n.14.

B. AAM Does Not Challenge the Act’s Penalty Provision.

The district court’s finding that the Act’s penalty provision is “fundamentally at odds with dormant Commerce Clause jurisprudence,” which AAM echoes here, is not supported by the case law. Add. 16.; Resp. Br. 48-49. PhRMA made a similar argument in *Walsh*, where Maine’s law imposed a “choice” on out-of-state manufacturers: offer rebates on their drugs in Maine, or else Maine will require customers to obtain prior authorizations before purchasing their drugs in Maine. 538 U.S. 662. Those conditions were irrelevant, the Court noted, because “the alleged harm to interstate commerce would be the same regardless of whether manufacturer compliance is completely voluntary or the product of coercion.” *Id.* at 669

In any event, while the Act prohibits specific withdrawal of *products* from the market, it does not penalize manufacturers from voluntarily surrendering their licenses, and thus stepping away from the Minnesota marketplace entirely. AAM’s members may prefer not to do this, but their desire to be free of state regulation, at no cost to themselves, is not a concern protected by the Constitution.

C. This Court Should Ignore AAM’s Attempt to Weave *Pike* Balancing Arguments Into this Appeal.

AAM contends that they have submitted undisputed evidence that they cannot segregate drugs by destination state, or that they cannot identify their drugs final

destination. Resp. Br. 44.¹⁷ But this is an argument about the purported burden of the Act and AAM’s *Pike* balancing claim is not on appeal.

Additionally, the Act is not to blame for imposing these logistical challenges on generic drug manufacturers. AAM’s members’ reliance on a wholesale distribution network dominated by the Big Three is a result of their own choices. Here, manufacturers clearly *can* sell directly into states, they just choose – in most instances – not to do so. *Online Merchants Guild v. Cameron*, 995 F.3d 540, 556 (6th Cir. 2021) (finding that it was “Amazon’s decision to structure its online marketplace to allow only a single, national price while preventing third-party sellers from limiting the states in which their goods are sold,” but “the law’s effect on out-of-state commerce would be virtually nonexistent but for Amazon’s limitations on third-party sellers.”). In other words, a regulated industry cannot immunize itself from state regulations by pointing to the complexities posed by the byzantine distribution process it has chosen to erect or rely on.

¹⁷ AAM’s evidence is less conclusive than they claim. Virtually every assertion is qualified by what their members “typically” do and how they “typically” operate in the “majority” of cases. *See* 4-App.-647-648 (R.Doc. 17 ¶¶ 4-7); 4-App.-656 (R.Doc. 19 ¶¶ 4-6). Their declarations’ reference to “feasibility” is only mentioned in relation to the Act’s speculated impact on planned price increases; not their ability to segregate drugs by destination state. *See* 4-App.-649 (R.Doc. 17 ¶¶ 11, 16); 4-App.-659 (R.Doc. 19 ¶¶ 16-17.) At least one of the manufacturers admits they sell products to “hospital systems, physicians, or specialty pharmacies with a physical presence in Minnesota.” 4-App.-656 (R.Doc. 19 ¶ 4.)

D. AAM's Attempts to Diminish and Distinguish Minnesota's Drug Manufacturer Licensure Requirements Are Unavailing.

AAM fails to distinguish the Act's reach to out-of-state manufacturers from the identical out-of-state reach imposed by Minnesota's prescription drug regulatory scheme, of which the Act is a part. Resp. Br. 30 n.20, 36. AAM wrongly diminishes the importance of Minnesota's drug manufacturer licensing scheme.

First, contrary to AAM's claims, the Act and Minnesota's manufacturer licensing requirements apply to the conduct of out-of-state manufacturers in the same way and extent. Both apply only to the extent the out-of-state manufacturer chooses to access Minnesota's market by shipping its drugs into Minnesota, either directly or indirectly through an intermediary. *Compare* Minn. Stat. § 151.252, subd. 1(g) (requiring license for each out-of-state facility “at which drugs that are shipped into the state are manufactured”); *with* § 62J.842 (prohibiting manufacturer from imposing excessive price increases, directly or indirectly, on any generic drug sold, dispensed, or delivered to any consumer in the state”) (*see also*, 3-App.-483; (R.Doc. 27 at 2, ¶¶ 3-6). And neither the Act, nor Minnesota's manufacturer licensing requirements apply to out-of-state manufacturers actions or conduct directed at any other state's market.

Second, AAM has it exactly backwards when it claims licensure is “a far weaker connection than in-state residence.” Resp. Br. 36. AAM fails to recognize (as explained *supra*) that a residency-only connection with Minnesota can have

overbroad applications and capture out-of-state actors that never “stepped foot in” or sought to avail themselves of Minnesota’s market. The polar opposite is true for licensure, which (like the Act) is only triggered by out-of-state manufacturers affirmatively setting foot in Minnesota, availing itself of the marketplace by shipping (directly or indirectly) its generic drugs into Minnesota. AAM’s members undisputedly have done so, and continue to do so, and so long as they continue to affirmatively seek to profit from Minnesota’s marketplace, they must comply with Minnesota’s laws.

The Act does not pose overbreadth concerns, which again, only regulates out-of-state manufacturers to the extent they sell, dispense, or deliver their excessively priced generic drugs to consumers in Minnesota. Contrary to AAM’s claims, the State has strong police power interests in locally regulating its own marketplace and ensuring the health and safety of in-state consumers are protected when out-of-state manufacturers extend their generic drug products to them.

CONCLUSION

Consider the import of upholding the district court’s decision: despite purposely directing their products to a particular state, any out-of-state manufacturer could avoid a state’s regulatory requirements simply by placing another out-of-state intermediary between them and the regulating state. State-level regulatory regimes

would collapse, companies would race to the regulatory bottom by relocating to the state with the least restrictive laws.

In our interconnected national economy, failing to vacate the district court's injunction would substantially diminish the sovereign power of states to determine which goods may be brought into and consumed within their territorial boundaries. For all these reasons, the Court should reverse the district court's preliminary injunction and remand for further proceedings.

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Respectfully submitted,

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WITH FRAP 32**

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/s/ Nick Pladson

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The undersigned, on behalf of the party filing and serving this brief, certifies that the brief has been scanned for viruses and that the brief is virus-free.

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